



UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1631

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-226 are pending in the instant application. . Claims 40-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Appellant timely traversed the restriction (election) requirement in the reply filed on 28 November 2007.

Claims 1-39 and 112-226 are appealed herein. However, it is noted that claims 20-22, 25-36, 39, 113-119, 121, 125-134, 156-158, 161, 165-174, 176-178, 181, 185-194, 216-218, and 222-224 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The outstanding rejection under 35 USC 102(b) over Kovatchev et al (Diabetes Care (1997) Vol. 20, No. 11, pages 1655-1658) is hereby withdrawn in view of Appellant's arguments. Specifically, the prior art does not teach the limitation of estimating HbA_{1c} from the preprocessed blood glucose (BG) data. Rather, the prior art only

Art Unit: 1631

teaches the transformation of BG data to convert it to derived data. As such, the rejection is withdrawn.

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

6,421,633

Heinonen et al.

7-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

I. Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, 112, 113, 135-154, and 195-214 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is maintained from the Office Action of 6 April 2010.

Claims 1-18, 112, 113, 135-154, and 195-214 are drawn to methods for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data comprising the

Art Unit: 1631

steps of pre-processing data, estimating HbA_{1c}, validating the estimate, and transforming the estimate to a visual depiction for output.

Based upon consideration of all of the relevant factors with respect to the claim as a whole, the instant claims are held to claim an abstract idea, and are therefore rejected as ineligible subject matter under 35 U.S.C. 101. The rationale for this finding is explained below:

Making reference to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process claim include: a) no express or inherent recitation of a machine or transformation in said claim; b) recitation of a mere statement of a general concept, such that it includes, for example, the mathematical concepts of processing, estimating and transforming, in said claim; and c) recitation of a transformation with said steps that is merely tangentially related to the performance of said steps.

In the instant case, the claims are not patent eligible under the *Interim Guidance* because the claims do not include an express or inherent recitation of a specific machine to perform the method of evaluating the HbA_{1c} of a patient. Further, with reference to b), above, the claims merely recite mathematical concepts of manipulating data by pre-processing data to convert it to a derived data, estimating the HbA_{1c} from a predetermined formula, and validating the estimate without the recitation of a machine in which to perform such steps. Finally, with reference to c), above, the recitation of “electronically transforming the estimate into a visual depiction” is not material to or central to the purpose of the claimed subject matter and does not constitute a transformation to a different state or thing. The recitation is tangentially related to the performance of the evaluation of HbA_{1c}, which is calculated by conversion of the collected BG

Art Unit: 1631

data, and estimated by applying a predetermined formula. The instant claim estimates are not generated by a specific machine and therefore do not represent a claimed process that “is limited to a practical application of a fundamental principal to transform *specific* data” (*In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (P. 26, Federal Circuit, 2008)). The data herein can be computed by any general purpose computer and therefore cannot be statutory.

As such, the claims are non-statutory.

II. Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8-10, 24, 26-28, 120, 122-124, 140, 142-144, 160, 162-164, 180, 182-184, 200, 202-204, 220, and 226 and those claims dependent therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained from the Office Action of 6 April 2010.

Each of the recited claims above and those claims dependent therefrom recite, “using a predetermined mathematical formula defined as”. The claims are vague and indefinite because each of the recited claims fails to recite any such mathematical formula. Rather, the claims merely define certain criteria, such as “scale” and “risk” etc...without any association to an actual formula and therefore it is unclear as to what is being computed. Clarification through the recitation of an *actual* formula is requested. As such, the claims are indefinite.

Art Unit: 1631

It is noted that claims 11, 29, 39, 112, 114, 125, 145, 165, 185, and 205 and the claims dependent therefrom are definite, as they actually recite a mathematical formula defined by $HbA_{1c} =$ to the EST2 and $HbA_{1c} =$ to $0.809098 * BGMM1 + 0.064540 * RLO1 - 0.151673 * RHI1 + 1.873325$ wherein the estimating is defined by the formula.

III. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 19, 37, 38, 135, 155, 175, 195, 215, and 221 are rejected under 35 U.S.C. 102(e) as being anticipated by 6,421,633 (Heinonen et al.; July 16, 2002 with priority to May 21, 1998). This rejection is maintained from the Office Action of 6 April 2010.

The instant claims are drawn to methods for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data comprising the steps of pre-processing data, estimating HbA_{1c} , validating the estimate, and transforming the estimate to a visual depiction for output.

Heinonen et al. teach a method and system whereby levels of HbA_{1c} are predicted using a mathematical model which is derived to predict the behavior of HbA_{1c} relative to blood glucose

As such, the claims are anticipated.

(10) Response to Arguments

I. Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

1. Appellant argues that “the appealed claims in this case are not directed to abstract intellectual concepts such as converting binary-coded-decimal numbers to binary numbers, as in Gottschalk v. Benson, 409 U.S. 63, 175 USPQ 673 (1972).” Appellant further states that “neither are the claims directed to mental processes, such as managing the consumption risk costs of a commodity, as in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).” Appellant further asserts that “neither are the claims directed to phenomena of nature, such a properties of inhibition or of non-inhibition in Rhizobia bacteria, as in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).”

Rather, Appellant states, “the appealed claims [are] to a specific method of estimating the glycosylated hemoglobin of a patient and communication of the estimate to a user, [which] is directed to a method that pertains to analysis of quantitative physical characteristics of a physical patient, and that has a practical application in the prevention or treatment of an adverse physical condition of a patient”. Appellant argues that “because the claimed method is applied to data representative of the physical (emphasis added by Appellant) element of a patient’s blood composition, it meets the “transformation” test because it converts SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin”.

Art Unit: 1631

This is not persuasive. In accord with and making reference to the *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos* (75 FR 43922 at 43927 (27 July 2010)), factors that weigh against the eligibility of a process claim include: a) no express or inherent recitation of a machine or transformation in said claim; b) recitation of a mere statement of a general concept, such that it includes, for example, mathematical concepts processing, estimating and transforming, in said claim; and c) recitation of a transformation with said steps that is merely tangentially related to the performance of said steps.

In the instant case, as detailed above, the claims do not meet the analysis. The claims do not, as Applicant seems to indicate, meet the transformation test by merely taking *data representative* of the physical element of a patient's blood and converting it to another type of data (SMBG data) because no transformation has taken place. The claims do not recite a step of “collecting”, for example. The claims, rather, use “data” that is “based on” collected blood. The “transformation” has already taken place before said method, as it is the “data” that are “pre-processed” and “estimated”. The fact remains that the “data” are still “data” in the steps of the claim. The “pre-processing” of the collected BG data does not transform the data to a different state or thing. If the claims recited a step of “collecting a blood sample from a patient” and then went on to “process the blood to calculate BG data” and then to further use that data in the remainder of the claimed method steps, for example, the claim would meet the “transformation” arm of the test.

Art Unit: 1631

2. Appellant asserts that “the transformation” part of the test is met where the data represents physical and tangible objects, and electronic transformation of data into a visual depiction (Appellant reciting Abele, 684 F.2d at 908-09).

This is not persuasive. The “transformation” language, such that the data are “electronically transformed” to a “visual depiction” does not provide transformation to a different state or thing as it is the data that are central to the claim elements and providing a depiction is merely tangential to the performance of said data steps. The transformation recited is not transformation of “physical” data, because nothing was physically collected and then “transformed”. For example, physical blood was not “collected” and then transformed to get the data value. Further, the instant Specification, at page 11, lines 16-18, states that “pre-processing” of data includes “using mathematical formulae” and therefore, the pre-processing step does not include “collection” of a physical sample that is then transformed, that would constitute a “transformation” to a different state or thing. See also the example at page 57 in which pre-processing is disclosed as “pre-processing of *data*”.

In addition, the electronic data never changes, although is visually displayed. The digital data is only manipulated in the claimed method. This is contrast to the facts in *Abele*, in which the claims are directed to X-ray attenuation data that is produced by a specific machine, i.e. a computed tomography scanner. The data therein (as recited from *Bilski*) “clearly represented physical and tangible objects, namely the structure of bones, organs and body tissue. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly claimed process patent eligible”. Such is not the case herein. The data, as stated above, has not been changed in the claimed method steps to

Art Unit: 1631

represent a physical object. The “digital data” from Abele was actually transformed into depiction of a physical object, i.e. bones, organs, body tissue. The digital data herein does not represent any such physical structure other than the data that was originally input. The claims remain non-statutory.

II. Claim Rejections - 35 USC § 112-2nd paragraph

1. Appellant argues that “the Office action erroneously states that the claims define merely certain criteria without any association to an actual formula [and] to the contrary, actual mathematical formulae are in fact set forth in the claims under rejection”. Appellant further states that “for example, claim 6 requires that Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) be computed using predetermined mathematical formula defined as $RLO1 = \text{average of RiskLO per patient}$, and $RHI1 = \text{average of RiskHI per patient}$ [and that] these are actual mathematical formulae”.

This is not persuasive. The recitation of $RLO1 = \text{average of RiskLO per patient}$, and $RHI1 = \text{average of RiskHI per patient}$, as well as the other claim parameters, as set forth, for example, in claim 6, are merely definitions of the recited claim terms (RLO1 and RHI1 being defined as an average risk) and are not mathematical formulae. The definitions merely disclose what these terms represent without giving parameters/values such that they can actually be calculated. There is no recited formula containing all of the said terms such that a solution could be calculated. There is nothing to indicate how they relate each to the other such that a “formula” is set up in order to calculate High Blood Glucose or a Low Blood Glucose, for

Art Unit: 1631

example. What is the fixed relationship between the certain quantities that yields a solution?

Without such in the claims, the claims are indefinite.

III. Claim Rejections - 35 USC § 102

1. Appellant argues that “Heinonen does not pre-process collected BG data to convert the collected BG data into derived BG data derived from the collected BG data; estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data; validate the estimate via sample criteria; electronically transform the estimate into a visual depiction; or output the visual depiction of the estimate to a user as required by the claims on appeal”.

This is not persuasive. Heinonen teaches a method and system for predicting the level of HbA_{1c} in a patient’s blood using BG levels (column 2, lines 21-25). This includes deriving a mathematical model of the behavior of the HbA_{1c} component level relative to the BG level using previously measured levels. The BG levels are measured over time and pre-processed using a gaussian function to model the distribution of the blood glucose levels (from low to high at given times, e.g. a distribution) (column 3, lines 4-19). The mathematical model relates the BG data to predict (estimate) the HbA_{1c} (column 2, lines 54-60). The data are validated by recalculation of modeling coefficients based on levels attained previously (sample selection criteria-defined in the Specification to be a “test frequency” criteria at page 13, lines 13-17). Finally, the data are visually depicted (column 4, line 25-central computer; column 7, line 33-34-central computer; column 7, lines 54-61-transmission to a patient for display) and output to a user (column 7, line 55-61-transmission to a patient). As such, Heinonen anticipate said claims.

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637